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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,990	01/30/2004	Borje Sellergren	74239	1989

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ALBIHNS STOCKHOLM AB
BOX 5581, Linnegatan 2
SE-114 85 STOCKHOLM; Sweden
STOCKHOLM,
SWEDEN

EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/707,990	SELLERGREN ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are pending and require restriction. Applicant's preliminary amendment, filed February 10, 2004, is acknowledged, wherein claim 9 has been amended.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method of producing a molecularly-imprinted peptide material, classified in class 530, subclass 334.

II. Claims 1, 3, 5, and 6, drawn to a method of producing a molecularly-imprinted oligosaccharide material, classified in class 435, subclass 72.

III. Claims 1, 3, 5, and 6, drawn to a method of producing a molecularly-imprinted oligonucleotide material, classified in class 435, subclass 91.1.

IV. Claims 7 and 8, drawn to a method of using a molecularly-imprinted peptide material, classified in class 530, subclass 334.

V. Claims 7 and 8, drawn to a method of using a molecularly-imprinted oligosaccharide material, classified in class 435, subclass 72.

VI. Claims 7 and 8, drawn to a method of using a molecularly-imprinted oligonucleotide material, classified in class 435, subclass 91.1.

VII. Claim 9, drawn to a chromatographic stationary phase comprising a molecularly-imprinted peptide material, classified in class 530, subclass 334.

VIII. Claim 9, drawn to a chromatographic stationary phase comprising a molecularly-imprinted oligosaccharide material, classified in class 435, subclass 72.

IX. Claim 9, drawn to a chromatographic stationary phase comprising a molecularly-imprinted oligonucleotide material, classified in class 435, subclass 91.1.

It is noted that the compounds claimed in Groups VII-IX are peptides, however, the claim has been divided according to the recitation of 'peptide', 'oligosaccharide', and 'oligonucleotide' and that claim 9 would lack proper antecedent basis if Applicant were to elect from Groups VIII or IX.

Inventions I-III and VII-IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one could make the products of inventions VII-IX by solution phase peptide synthetic methods or by cellular protein expression and extraction methods.

Inventions VII-IX and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in the materially different process of protein synthesis, antibody generation, or as analgesics.

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of making structurally distinct molecules and are not capable of

use together. One would not use the same techniques, conditions, and/or reagents in each of the unrelated methods.

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of using structurally distinct molecules and are not capable of use together. Each method has a different function/effect/mode of operation, in that each is suitable for separation of a structurally distinct product.

Inventions VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the stationary phase is structurally distinct, one from another, and each would necessarily have a different function/mode of action/effect, e.g.- peptide phase for separating proteins, nucleotide phase for separating DNA/RNA, etc..

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility.

In the instant case, the compounds of claims 4, 9, and the 'peptide epitope' of claim 2 do not share a common structural feature disclosed as essential to the utility. Accordingly, Applicant is required to select a single peptide as the peptide of the compound/compound of the method, as drawn to the elected invention, regardless of which group is elected. [Note: A generic (e.g.- peptide epitope, etc.) may NOT be selected as drawn to the elected invention because no

meaningful search can be conducted without an undue burden, due to the myriad of potential substitutions possible in each formula]. The peptides disclosed in claims 4 and 9 and the 'peptide epitope' of claim 2 were not found to share a significant structural core from which a meaningful coextensive search could be conducted, thus a separate and distinct search, as well as examination, of each peptide sequence is required. In order to effect a complete response to this Office Action, Applicant is required to select a single peptide and identify claims readable upon the elected peptide, including any claims subsequently added. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each peptide is assumed to be a patentably distinct invention, in the absence of specific, substantial, and credible evidence to the contrary**.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants, or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence, or admission, may be used in a rejection under 35 U.S.C. § 103(a) of the other.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. For example, the search for art pertaining chromatographic stationary phases comprising nociceptin would not necessarily lead to the discovery of all pertinent literature for methods of making peptide stationary phases or nucleotide stationary phases.

Additionally, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making. For example, the search for FMOC-Phe-Si would not necessarily lead to the discovery of nociceptin, nor would it lead to the discovery of all compounds embraced by the broad generic claims.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

This application contains claims directed to the following patentably distinct species of the claimed inventions:

disposable surface activated support; and
monomer mixture.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-4 and 6-9 are generic, with regards to 'disposable surface activated support', and claims 1-5 and 7-9 are generic to 'monomer mixture'.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 1, 3, and 5-9 are generic to a plurality of disclosed patentably distinct species comprising oligonucleotides and oligosaccharides. If Applicant elects from any of Groups II, III, V, VI, VIII, or IX, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each oligosaccharide or oligonucleotide, commensurate with the elected group, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37 C.F.R. § 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 148(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Andrew D. Kosar, Ph.D.
Patent Examiner
Art Unit 1654